



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/402,737 10/08/99 NEUSER

D BAYER10197

EXAMINER

HM12/0321

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GEORGE, K
ART UNIT PAPER NUMBER

1616
DATE MAILED:

03/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/402,737 | NEUSER ET AL. | |
| | Examiner | Art Unit | |
| | Konata M. George | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-4 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claims ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are objected to by the Examiner.
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). ____.
 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 20) Other:

DETAILED ACTION

Claims 1-4 are pending in this application.

Action Summary

1. The rejection of record under 35 U.S.C. 102(e) over Bourke et al. is hereby expressly withdrawn.

Response to Arguments

2. Applicant's arguments with respect to claims 1-4 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin (US 5,702,723).

Griffin ('723) discloses a multiple therapeutic substances delivered in a single pill for oral administration. The outer layer comprising an active substance of substance that will dissolve and have a beneficial effect somewhere is the mouth or upper respiratory area with the subsequent layers dissolving and the contained substances acting deeper within the body such as in the gastro-intestinal area or systemically (col. 3, lines 3-13). The prior art discloses several examples throughout the specification, one specific example comprises a pain reliever that has a rapid absorption and an

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antihistamine with acts systemically (col. 4, lines 24-36). The prior art does not disclose a time of onset action or that the composition also contains ancillary substances and carriers.

However, it would have been obvious to one of skill in the art at the time the invention was made to add ancillary substances and carriers since it is known that carriers and ancillary substances are substances that are added to pharmaceutical compositions. It is also obvious to one of skill in the art to realize that the local acting would have a quick duration of action and the systemic acting drug will have a longer duration of action.

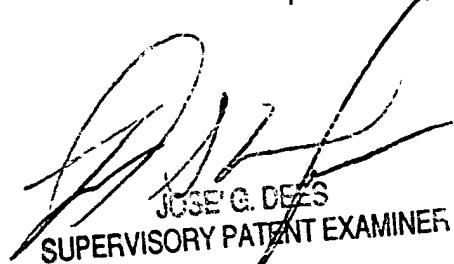
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

KMG


JOSE G. DEES
SUPERVISORY PATENT EXAMINER

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